

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS
et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant.

Civil Action No. 16-cv-11985-IT

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Fed. R. Civ. P. 56 and Local Rule 56.1, the plaintiffs, American Academy of Pediatrics, Massachusetts Chapter of American Academy of Pediatrics, Inc., American Cancer Society, Inc., American Cancer Society Cancer Action Network, Inc., American Heart Association, Inc., American Lung Association, Campaign for Tobacco-Free Kids, Truth Initiative Foundation d/b/a Truth Initiative, Dr. Ted Kremer, Dr. Jonathan Winickoff and Dr. Lynda Young move for summary judgment on all counts of their Complaint against the defendant United States Food and Drug Administration ("FDA") because there are no genuine issues of material fact and they are entitled to judgment as a matter of law. In support of their motion, they state as follows:

1. The Court is required by § 706(1) of the Administrative Procedure Act ("APA") to compel FDA to issue the graphic warnings rule that FDA was required to issue by June 22, 2011 under the Tobacco Control Act, but has unlawfully withheld.
2. The Court is required by § 706(1) of the APA to compel FDA to issue the graphic warnings rule that FDA was required to issue by June 22, 2011 under the Tobacco Control Act, but has unreasonably delayed.
3. If the Court declines to grant relief under the APA, the Court should invoke the federal mandamus statute, 28 U.S.C. § 1361, and compel FDA to issue the graphic warnings rule that FDA was required to issue by June

22, 2011 under the Tobacco Control Act because the plaintiffs have a clear and indisputable right to relief; FDA is continuing to violate a clear duty to act; and, if relief is denied under the APA, there is no adequate, alternative remedy.

The Court should grant this motion and find that FDA has unlawfully withheld and unreasonably delayed its graphic warnings rule; issue an order requiring FDA to submit a proposed, expedited schedule for promulgation of a final rule, to be followed by an order establishing a fixed timetable for the completion of FDA's rulemaking; and retain jurisdiction to enforce FDA's compliance.

In support of this motion, the plaintiffs rely on their (a) Memorandum in Support of Motion for Summary Judgment; (b) Local Rule 56.1 Statement of Undisputed Facts; and (c) Appendix of Supporting Evidentiary Materials filed with this motion.

Request for Oral Argument

Pursuant to Local Rule 7.1(d), the plaintiffs request oral argument on this motion because they believe that oral argument may assist the Court in its consideration of this motion.

Local Rule 7.1(A)(2) Certificate

Counsel for the plaintiffs certify that they have conferred with opposing counsel and have been unable to narrow or resolve the issues raised by this motion.

By their attorneys,

/s/ Scott P. Lewis

Scott P. Lewis (BBO #298740)
Jessica A. Wall (BBO #689177)
ANDERSON & KREIGER LLP
50 Milk Street, 21st Floor
Boston, MA 02109
617-621-6500
slewis@andersonkreiger.com

Mark E. Greenwold (*pro hac vice*)
Dennis A. Henigan (*pro hac vice*)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I (Eye) Street, N.W., Suite 1200
Washington, DC 20005
202-296-5469
mgreenwold@tobaccofreekids.org

April 28, 2017

Certificate of Service

I hereby certify that this document filed through the ECF system was sent electronically to all counsel of record on April 28, 2017.

/s/ Jessica A. Wall